

IV ADMINISTRATION SET IDENTIFICATION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of Invention Disclosure Documents Nos.

5 481,332, filed October 16, 1999; and 498,899, filed August 22, 2001.

This application is a Continuation-in-Part of co-pending application Serial No. 09/971,179, filed October 4, 2001; which is a Continuation-in-Part of Application Serial No. 09/854,711, filed May 14, 2001, now abandoned.

10 FEDERALLY-SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

The present invention relates to a system for uniquely identifying each one of
15 two or more intravenous (IV) lines that may be simultaneously employed to deliver drugs intravenously to one or more patients respectively from two or more containers (such as IV bags or bottles).

There are medical situations, such as emergency rooms, trauma centers, and wards, in which two or more patients are simultaneously receiving IV drugs. Also, a
20 single hospital patient often requires the administration of multiple IV drugs delivered separately, but simultaneously, through two or more separate IV sets, at widely different dosage rates. In such situations, it is necessary to assure that each container of drug solution is properly matched to the correct IV line and from there to the correct patient. Confusion in matching these elements must be avoided to
25 assure that each drug is administered in the proper dosage to the proper patient, lest a patient be injured through the administration of the wrong drug or an improper dose

of the correct drug. Additionally, there have been numerous instances of contraindicated medications being introduced into an IV line at a "Y- site" or an in-line port, with possible endangerment of the patient. To date, efforts to avoid such confusion have largely been *ad hoc*. For example, medical personnel may attach
5 numbered pieces of adhesive tape to IV containers and to IV lines to match them up properly. Still, a more reliable mechanism has been sought to achieve these ends.

SUMMARY OF THE INVENTION

Broadly, the present invention is a system for identifying IV administration set
10 components, wherein the IV set includes an IV solution container, a drip chamber having a hollow spike for introduction into the container, and an IV line for delivering the IV solution to a patient, wherein the system comprises a first identification element that is removably attached to the drip chamber for subsequent attachment to the container; a second identification element permanently affixed to
15 the drip chamber; and a third identification element attached to a Y-site or port in the IV line.

In a specific preferred embodiment, the first identification element is a strip or patch that is adhesively attached to the drip chamber in a manner that will allow it to be removed therefrom for subsequent attachment to the IV solution container. The
20 second identification element is a marker, preferably a strip or a patch, that is permanently affixed to the drip chamber. The third identification element is attached to a Y-site or port that is part of the IV line. The third identification element may be an integral part of the Y-site or port, or it may be removably attached to it. The first, second, and third identification elements bear matching identification symbols. In
25 the context of this invention, the term "symbol" is deemed to encompass one or more letters, numbers, geometric shapes, abstract shapes, colors, and any

combination of these elements. The term "symbol" may also include a color alone.

Viewed another way, the system of the invention comprises a matched set of plural identification elements bearing matching identification symbols, wherein a first one of the set is attachable to the IV container; a second one of the set is attached to the drip chamber; and a third one of the set is attached to the IV line remote from the first and second identification elements in the set. In practice, the system will advantageously include two or more such matched sets of identification elements, each set bearing a unique identification symbol. In the context of this invention, however, the term "system" is meant to encompass one or more such matched sets of identification elements.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an elevation view of an IV administration set identification system in accordance with a first embodiment of the present invention, showing the system in use on a typical IV administration set;

Figure 2 is an elevational view of the first identification element of the IV set identification system used on the IV administration set of Figure 1;

Figure 3 is an elevational view of the second identification element of the IV set identification system shown in Figure 1;

Figure 4 is an elevational view of the third identification element of the IV set identification system shown in Figure 1;

Figures 5, 6, 7, and 8 are elevational views of identification elements showing alternative types of identification symbols;

Figure 9 is a side elevational view of a third identification element that is removably attached to a Y-site or port, in accordance with a second embodiment of the invention;

Figure 10 is a front elevational view of the third identification element of Figure 9 and the Y-site or port to which it is removably attached, taken along line 10 - 10 of Figure 9;

5 Figure 11 is a bottom plan view of the third identification element of Figure 9 and the Y-site or port to which it is removably attached, taken along line 11 - 11 of Figure 10;

Figure 12 is a perspective view of another form of the third identification element in accordance with the second embodiment of the invention, showing it in an open position; and

10 Figure 13 is a perspective view of the third identification element of Figure 12, showing it in a closed position.

DETAILED DESCRIPTION OF THE INVENTION

Referring first to Figure 1, a typical IV administration set 10 is shown,
15 comprising a flexible plastic bag 12 serving as a container or reservoir for an IV drug solution (not shown). The set 10 also includes a drip chamber 14 having a hollow needle or spike 16 adapted to puncture the bag 12. The drip chamber 14 has an outlet 18 that communicates with a first segment 20 of a flexible IV line. The first IV line segment 20 has an outlet end that communicates with a first inlet branch 22 of a
20 Y-shaped port or "Y-site" 24. The Y-site 24 is modified in accordance with the present invention, as will be described below. The Y-site 24 may advantageously have a second inlet branch 26 sealed by a puncturable septum 28. The septum 28 may be punctured by the needle of a syringe (not shown), or opened by a Luer connector or other device (not shown), for the administration of a supplemental drug
25 into the IV line through the second inlet branch 26, as is well known in the art. The Y-site 24 has an outlet branch 30 that communicates with a second segment 32 of the

flexible IV line, which terminates in an IV needle (not shown) that is adapted for insertion into a vein of a patient (not shown). Preferably, the outlet branch 30 is aligned axially with the second inlet branch 26, so as to form therewith a continuous tubular body.

5 A first embodiment of the identification system of the present invention is shown in Figures 1, 2, 3, and 4. The system comprises a first identification element, in the form of a first adhesive patch or strip 38 (Figure 2); a second identification element, preferably in the form of a second adhesive strip or patch 40 (Figure 3); and third identification element, in the form of a flattened extension 42 that extends
10 outwardly from the tubular body that comprises the second inlet branch 26 and the outlet branch 30 of the Y-site 24, and that is advantageously formed integrally therewith (Figure 4).

The first adhesive strip or patch 38 (Figure 2) includes a pull tab 48 at one end and an adhesive backing 50 on its reverse side, but not on the back of the pull tab 48.

15 The first adhesive strip or patch 38 is initially adhesively attached to the drip chamber 14 (as shown in Figure 2 and in solid outline in Figure 1). When the identification system of the present invention is used, however, the first adhesive strip or patch 38 is removed from the drip chamber 14 by means of the pull tab 48, and it is then adhesively applied to the exterior of the IV container 12, as shown in broken
20 outline in Figure 1.

The second adhesive strip or patch 40 also has an adhesive backing 44 (Figure 3) that allows it to be fixed to the drip chamber 14 (as shown in Figure 1). The adhesive backing 44 is advantageously such as to fix the second strip or patch 40 permanently to the drip chamber 14 as a permanent marker. Alternatively, the
25 second identification element may simply be an identification symbol permanently marked on the drip chamber.

The first adhesive strip or patch 38, the second adhesive strip or patch 40, and the coupler extension 42 are each marked with a matching identification symbol 46. As shown in Figures 1, 2, 3, and 4, the symbol 46 may be a numeral. Preferably, color may be used as part of the identification symbols 46, whereby the symbols 46 have a matching color as well as a matching number. Still more preferably, the Y-site 24 may be made in the same color as the symbols 46.

In use, the identification system of the present invention will usually comprise two or more sets of identification elements, each set comprising a first strip or patch 38, a second strip or patch 40, and a Y-site 24 with an extension 42 bearing the same identification symbol 46, unique to that set.

Figures 5, 6, and 7 show alternative forms of the identification system, using different types of identification symbols. In Figure 5 the symbol 46' is a letter, preferably in combination with a matching color. In Figure 6 the symbol 46" is a color alone, the matching color being the predominant (if not sole) color of both the tab 42 and the strip 40. In Figure 7 the symbol 46'" is a colored geometric shape. Still other types of symbols may be Roman numerals, abstract shapes and designs, and letters of non-Latin alphabets.

Figure 8 illustrates an alternative form of the third identification element. In this form, the coupler or Y-site 52 is structurally an ordinary device of this type, lacking the extension 42 described above. The Y-site 52 is marked with an identification symbol 54 by means of a band 56 attached around the inlet branch of the coupler 52, the band 56 bearing the symbol 54. The band 56, which thus constitutes the third identification element, is preferably applied as a segment of shrink tubing, but it may also be in the form of an adhesive strip.

In use, the practitioner is provided with a drip chamber 14 to which the first identification element 38 is removably attached and the second identification element

40 is permanently fixed, and an IV line 20 having a Y-site or port 24 that includes the third identification element in the form of the integral extension 42 or the band 56.

When an IV solution container 12 is selected, the drip chamber 14 is connected to the IV solution container 12 (by means of the hollow spike 16). The first

5 identification element 38 is then removed from the drip chamber 14 and attached to the IV solution container 12. In this manner, a high degree of certainty is provided that the IV solution container is matched to the proper IV line.

Figures 9, 10, and 11 illustrate another embodiment of the invention, in which the third identification element is in the form of an attachment 60 that is removably

10 attachable to a standard Y-site 62 having a first inlet branch 63a and a second inlet branch 63b. The attachment 60 comprises a sleeve 64 with an axial slit 66 and an integral lateral extension 68 that is marked with an identification symbol 70. The integral extension 68 is preferably located diametrically opposite the axial slit 66, and it is oriented substantially parallel to the slit 66. The sleeve 64 is made of a resilient,

15 flexible, plastic material, and it is shaped and dimensioned to fit over and to conform to the exterior surface of the Y-site 62. The sleeve 64 can thus be slightly spread apart along the axial slit 66 to allow the second IV line 32 downstream from the Y-site 62 to be passed through the slit 66, and then the attachment 60 is pushed upwardly from the lower (downstream) end of the Y-site 62 until the Y-site 62 is

20 received in the sleeve 64. The sleeve 64 is widened at its upper (upstream) end to accommodate the first inlet branch 63a of the Y-site 62. Likewise, the slit 66 is widened at its upper (upstream) end to accommodate the second inlet branch 63b of the Y-site 62. The attachment 60 may be removed by just reversing the

25 aforementioned installation process. Alternatively, the attachment 60 can be installed snapping the sleeve 64 directly onto the Y-site 62 by spreading the sleeve 64 apart along the slit 66. Likewise, the sleeve 64 can be spread apart along the slit 66

for removal from the port or Y-site 62.

Figures 12 and 13 illustrate another form of a removable snap-on attachment 80 that functions as the third identification element in the second embodiment of the invention. The attachment 80 comprises first and second mating sections 82a, 82b, respectively, joined by an integral hinge 84. Each of the sections comprises a trough-like portion 86, semicircular in cross-section, adjacent to, and aligned along, the hinge 84; and a flat, tabular portion 88 extending outwardly from the trough-like portion 86. Each of the trough-like portions 86 has a substantially semicircular cut-out 90 in the side adjoining the hinge 84. The tabular portion 88 of the first section 82a includes an aperture 92, while the tabular portion 88 of the second section 82b includes a post or peg 94 that is configured and dimensioned to snap into the aperture 92 with a friction fit.

As shown in Figure 13, the first and second sections 82a, 82b are foldable toward each other along the hinge 84, so that the tabular sections 88 fold flat against each other, with the snap-together engagement between the peg 94 and its mating aperture 92 holding the two sections together. In this closed or folded configuration, the trough-like portions 86 together form a tubular sleeve 96 that is shaped and dimensioned to fit over and to conform to the exterior surface of the standard Y-site 62, of the type described above with reference to Figures 8, 10, and 11. Also, with the attachment 80 in its folded position, the cut-outs 90 form a substantially circular hole 98 that is dimensioned to receive the second inlet branch 63b of the Y-site or port 62, while the tabular portions 88 form an extension 100, on the outer surface of which a symbol 102 may be provided. Thus, the attachment 80 is placed over the Y-site or port 62, so that the second inlet branch 63b extends through the cut-outs 90, and the sections 82a, 82b are folded together along the hinge 84, and snapped together using the peg 94 and the mating aperture 92, whereby the attachment 80 is

secured to the Y-site or port 62 with the second inlet branch 63b extending through the hole 98 formed by the cut-outs 90.

The method of using the second embodiment of the invention is the same as that described above for the first embodiment, except that the practitioner is provided with an IV line having a standard Y-site or port 62 and an appropriate snap-on attachment 60 or 80 for attachment to the Y-site or port 62. When an IV solution container 12 is selected, the drip chamber 14 is connected to it, and the first identification element is removed from the drip chamber and applied to the solution container. The third identification element (the attachment 60 or the attachment 80) is then attached to the Y-site or port 62 (as described above), the attachment 60 or 80 having an identification symbol 70 or 102 that matches the identification symbol on the first and second identification elements.

While preferred embodiments of the invention have been described herein, it will be appreciated that a number of variations and modifications will suggest themselves to those skilled in the pertinent arts. These variations and modifications are considered within the spirit and scope of the invention, as defined in the claims that follow.